

Application No.: 10/580,882
Filing Date: May 26, 2006

REMARKS

Claim 1 has been amended. Claims 5-9 are cancelled. New claims 10-11 are added. New claims 10-11 find basis in cancelled claims 8 and 9. Claims 1-4 and 10-11 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed in more detail below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 102(b)

Claims 1-4 and 7-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Suzuki, et al. (JP 11246339A).

The limitation of claim 6 has been incorporated into claim 1. Claim 6 is not subject to this ground of rejection. Accordingly, the claims as amended are not anticipated by Suzuki, et al. Further support for the amendment is found in the present specification at page 5, last 2 lines to page 6 line 2, page 12, line 4 and page 16, line 12.

In view of Applicants' amendments, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 5-6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Suzuki, et al. (JP 11246339 A) as applied to claims 1-4 and 7-9, above.

The limitations of claims 5 and 6 have been incorporated into claim 1. These limitations are not taught by Suzuki, et al.

Suzuki et al. disclose an external skin whitening preparation comprising 0.001-20.0% by mass of 4-n-butyl resorcinol and 0.0001-20.0% by mass (preferably 0.01-10% by mass) of extract of *Achillea millefolium*. While Suzuki, et al do not explicitly teach any compounds of Formula I, the Office Action asserts that such compounds are inherently present in *Achillea millefolium*.

Although Suzuki, et al. do not disclose anything regarding the content of a compound as represented by General Formula (I) of claim 1, such as centaureidin, in the *Achillea millefolium* extract used in their preparations, from the description of Suzuki, et al., the extract of *Achillea*

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millefolium used in Suzuki et al. is a commercially available extract of Western Saw Grass (*Achillea millefolium*) (see paragraph 0017 of Suzuki, et al.).

The present inventors have examined the content of centaureidin in commercially-produced extracts (just after extraction) and have determined that the centaureidin content is generally about 0.1% by mass (see the attached Declaration of Mr. Akihiro Tada)¹.

Suzuki, et al. disclose that 0.0001-20.0% by mass of extract of *Achillea millefolium* is contained in their external preparation (paragraph 0018). Based on this information and the analysis shown in the Tada Declaration, Applicants calculate that the composition of Suzuki, et al. will contain 1×10^{-7} to 0.02% by mass of centaureidin (compound of General Formula (I)).

The invention of amended claim 1 of the present application is an external preparation for skin, comprising a compound represented by the general formula (1) in a range of 0.035-2.0% by mass, and 4-n-butyl resorcinol in a range of 0.05-5% by mass. Applicants' claimed external preparations have significantly higher concentrations of centaureidin (compound of Formula (I)) than the preparations taught by Suzuki, et al.

Suzuki, et al. do not teach the claimed formulation. In fact, Suzuki, et al. teach away from the claimed concentration range. Suzuki, et al. teach that "even if it blends exceeding 20.0% of the weight, an increase in an effect cannot be expected on parenchyma and a tendency which becomes difficult also has combination to skin external preparations" (Paragraph 0018 of Suzuki, et al., English machine translation). Accordingly, Suzuki, et al. teach that there is no further benefit in increasing the concentration of the *Achillea millefolium* extract, and there may be some detrimental effect. One of ordinary skill in the art would have no reason to increase the concentration of the Western Saw Grass extract in light of the teaching of Suzuki, et al. that there was no added benefit in doing so and that there is a "tendency which becomes difficult". It is well established that a *prima facie* case of obviousness based on overlapping ranges may be overcome by showing that the art teaches away from the claimed range (see M.P.E.P. 2144.05

¹ Furthermore, it is known in the art that an extract of *Achillea millefolium* just after extraction is generally diluted to x100 when used as commercial products of *Achillea millefolium* extract. That is, the content of centaureidin in the composition of Suzuki, et al. may be still lower than the calculation provided in the Declaration. However, for purposes of argument and addressing the rejection, Applicants calculate the content of centaureidin in extract is about 0.1% by mass (maximum amount, without dilution).

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III). Such is the case here where Suzuki, et al. teach away from use of the higher concentrations claimed by Applicants.

Furthermore, the claimed preparation containing a compound of general formula (I) and 4-n-butyl resorcinol in the concentrations as claimed has the unexpected and advantageous effect of reducing the cytotoxicity of 4-n-butyl resorcinol (see Declaration of Akihiro Tada). This effect was not known or expected from Suzuki, et al.

In view of Applicants' amendments, arguments and the Declaration of Akihiro Tada, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
TOYA151.002APC	12/305350	SKIN EXTERNAL PREPARATION CONTAINING TRITERPENIC ACID	17-Dec-2008
TOYA151.003APC	12/305356	SKIN EXTERNAL PREPARATION HAVING EXCELLENT STABILITY	17-Dec-2008

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CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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